



Docket No. PHUS 288  
PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
FAOUR, J. et al.

Group Art Unit: 1617

Serial No.: 09/770,901

Examiner: S. Jiang

Filed: January 26, 2001

For: Pharmaceutical Compositions Containing  
a Cox-II Inhibitor and a Muscle Relaxant

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

<p><b>CERTIFICATE OF MAILING</b> <b>UNDER 37 C.F.R. § 1.8(a)</b></p> <p>I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on December 10, 2001.</p> <p>_____ Rick Matos (Typed or Printed Name)</p> <p>_____ (Signature)</p>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The following sections are submitted for this Information Disclosure Statement:

1. X Preliminary Statements
  2. X FORM PTO - 1449
  3. \_\_\_ Statement As To Information Not Found in Patents or Publications
  4. \_\_\_ Identification Of Prior Application In Which Information Was Cited And For Which No Copies Are Submitted Or Need Be Submitted
  5. \_\_\_ Cumulative Patents or Publications
  6. \_\_\_ Translation(s) of Non-English Language Documents
  7. X Concise Explanation of Non-English Language Listed Information Items
  8. X Copies of Listed Information Items Accompanying This Statement
  9. X Identification of Person(s) Making This Information Disclosure Statement
- Section 1. Preliminary Statements

Applicant submits herewith patents, publications or other information which may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The filing of this Supplemental Information Disclosure Statement shall not be construed as a representation that a search has been made (37 CFR 1.56(g)), or as an admission that the information cited is, or is considered to be, material to patentability.

The filing of this Supplemental Information Disclosure Statement shall not be construed as an admission against interest in any manner.

**Section 2. FORM PTO - 1449**

Form PTO - 1449 (2 pages) is enclosed herewith.

**Section 3. Statement As To Information Not Found In Patents Or Publications (Information not listed in PTO 1449)**

**Section 4. Identification Of Prior Application In Which Information Was Cited And for Which No Copies Are Submitted Or Need Be Submitted**

This application relies, under 35 U.S.C. 120, on the earlier filing date of prior application S/N \_\_\_\_\_, filed on \_\_\_\_\_.

**Section 5. Cumulative Patents or Publications**

\_\_\_\_\_ is cumulative of the following patents or publications listed on Form PTO 1449:

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In accordance with 37 CFR 1.98(c) a copy of only \_\_\_\_\_ is being submitted with this information disclosure statement.

**Section 6. Translation(s) of Non-English Language Documents**

\_\_\_\_\_ Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material.

☒ No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.

☐ The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

#### Section 7. Concise Explanation of Non-English Language Listed Information Items

Lipsky, P.E. (Ref. C1) discloses the recommendations for the clinical use of COX-2 inhibitors. The reference includes a proposed treatment approach based upon the recommendations of a panel of clinician for the use of COX-2 inhibitors in the management of pain. Applicants note that even the most recent recommendations do not include their combined administration with a muscle relaxant.

Cayetti et al. (Ref. C2) discloses the results of a study on the treatment of vertebral muscle contracture. The study included treatment of a first group with diclofenac (an NSAID) and pridinol (a muscle relaxant) and of a second group with clonixinate (a mixed COX-1/COX-2 inhibitor and 5-HETE inhibitor) and cyclobenzaprine (a muscle relaxant). They report that the tested drug combinations were efficacious in the model used but do not mention any observed synergistic analgesic effect. They do not suggest or disclose the combined use of a selective or specific COX-2 inhibitor with a muscle relaxant.

Congliandro (Ref. C3) discloses the results of a study on the treatment of muscle and joint inflammation accompanied by muscular contracture. The study included treatment of patients with a combination of benzydamine (NSAID), dibucaine (long-acting local anesthetic) and hyaluronidase (absorption enhancer, enzyme) with or without pridinol. Addition of pridinol improved the efficacy of the combination but no synergy was observed. They do not suggest or disclose the combined use of a selective or specific COX-2 inhibitor with a muscle relaxant.

Lanzara et al. (Ref. C4) discloses the results of a study on the treatment of muscular/arterial disorders caused by trauma. The study included treatment of patients with a combination of benzydamine, dibucaine and hyaluronidase with or without pridinol. They report that addition of pridinol improved the efficacy of the combination and provided a synergistic result. They do not suggest or disclose the combined use of a selective or specific COX-2 inhibitor with a muscle relaxant.

Section 8. Copies of Listed Information Items Accompanying This Statement  
Legible copies of all items listed in Form PTO-1449 accompany this information statement.

☐ Exception(s) to above

☐ Items in prior application from which an earlier filing date is claimed for this application as identified in Section 4.

\_\_\_ Cumulative patents or publications identified in Section 5.

Section 9. Identification of Person(s) Making This SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The person making this statement is

(a) \_\_\_ the inventor(s) who signs below.

\_\_\_\_\_  
Signature of Inventor

\_\_\_\_\_  
Typed name of inventor

(b) X the agent who signs below on the basis of:

\_\_\_ information supplied by the inventor(s)

\_\_\_ information supplied by an individual associated with the filing and prosecution of this application (37 CFR 1.56(c))

X information in the agent's file

It is respectfully requested that the references identified in this Supplemental Information Disclosure Statement be considered by the Examiner, be made a part of the official record, and be cited in the issued patent.

Respectfully submitted,

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